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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,407	01/17/2006	Laurent Meijer	040388-0131	4591

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EXAMINER	
SCHUBERG, LAURA J	
ART UNIT	PAPER NUMBER
1657	

MAIL DATE	DELIVERY MODE
10/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,407	MEIJER ET AL.	
	Examiner	Art Unit	
	Laura Schuberg	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-9 and 11-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-9,11-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/05/2007 has been entered.

Claims 1, 3-9 and 11-14 are pending and have been examined on the merits.

Response to Arguments

Applicant's arguments with respect to claims 1, 3-9 and 11-14 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3-9 and 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meijer (WO 01/41768 A2) in view of Santora et al. (US 2002/0173507) and Nicotera et al (US 2004/0019015 A1).

Claim 1 is drawn to a method for treating deafness in a subject comprising administering a pharmaceutical composition that comprises at least one kinase inhibitor that is a purine derivative or a pharmaceutically acceptable salt thereof and a pharmaceutically acceptable carrier, in an amount effective for inducing differentiation of supernumerary hair cells and Deiters' cells in an organ of Corti.

Claim 3 includes wherein the purine derivative is selected from roscovitine, indirubin and purvalanol.

Claim 4 includes wherein the kinase inhibitor is administered parenterally, rectally, topically, transdermally, or orally.

Claim 5 includes wherein the kinase inhibitors are administered by oral or injectable route.

Claim 6 includes different forms of the kinase inhibitor.

Claim 7 includes wherein the composition comprises 100-1000 mg of the kinase inhibitor per dose unit.

Claim 8 includes wherein the kinase inhibitor is administered in various forms.

Claim 9 includes wherein the injectable solution comprises 100-1000 mg of the kinase inhibitor or salt.

Claim 11 includes wherein the composition comprises 300-600 mg of the kinase inhibitor or salt per dose unit.

Claim 12 includes wherein the injectable solution comprises 300-600 mg of the kinase inhibitor or salt.

Claim 13 includes wherein the salt is an acid addition salt.

Claim 14 includes wherein the acid is selected from a group.

Meijer teaches a method of treating neurodegenerative disorders that includes the administration of cyclin-dependent kinase inhibitors such as roscovitine, purvalanol, or indirubin (page 1 lines 21-23, page 3 line 22). These are taught to be useful for treating Alzheimer's disease, Parkinson's disease OR other neuronal disorders (page 3 lines 21-27). The addition of a pharmaceutically acceptable carrier and acid addition salts such as acetic, ascorbic, maleic, phosphoric, salicylic and tartaric are taught as well as administration in various forms such as parenterally, rectally, topically, transdermally or orally (including injectable) (page 4 lines 15-30). For administration by the oral route, lozenges, compressed tablets, pills, tablets, capsules, drops, syrups, suspensions or emulsions may be used with the composition comprising 100-1000 mg of active principle per dose unit, preferably 300-600 mg (page 5 lines 1-4). Other forms

of administration include intravenous, subcutaneous or intramuscular route, formulated from sterile or sterilizable solutions and from suspensions and emulsions (page 5 lines 6-8).

Meijer does not specifically teach that hearing loss caused by nerve damage is a neurodegenerative disorder and thus treatable by the reference method.

Santora et al teach a method of treating neurodegenerative diseases with a CDK/cyclin kinase inhibitor (page 15 para 355-para 361). The neurodegenerative diseases are taught to include hearing loss as well as Alzheimer's and Parkinson's disease (page 15 para 361).

Nicotera et al teach a method of treating hearing loss with protein kinase inhibitors that can be administered orally, parenterally, subcutaneously, intravenously, intramuscularly and includes a pharmaceutically acceptable carrier in solid or liquid form, such as tablets, capsules, solutions, suspensions or emulsions (page 8 para 70). The dosage is taught to vary, but may include from about 50 mg to 1000 mg/kg of a protein kinase inhibitor, preferably 50-400 mg/kg (page 8 para 74).

Therefore, one of ordinary skill in the art would have been motivated to use the method of Meijer to treat hearing loss caused by nerve damage because Santora et al. teach that neurodegenerative disorders include hearing loss as well as Alzheimer's and Parkinson's disease and can be treated with a CDK/cyclin kinase inhibitor (page 15 para 361). While one of ordinary skill in the art might not have been aware of all the positive effects that the method of Meijer would have produced upon application to the treatment of hearing loss (i.e. inducing differentiation of supernumerary hair cells and

eiters' cells in an organ of Corti), these unexpected effects would have occurred upon administration of the purine derivatives as well as the expected prevention of cell death. One of ordinary skill in the art would have had a reasonable expectation of success because Nicotera et al teach using protein kinase inhibitors to treat hearing loss in the same formats as Meijer and at the same dosage.

Therefore, the combined teachings of Meijer, Nicotera et al. and Santora et al. render obvious Applicant's invention as claimed.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura Schuberg whose telephone number is 571-272-3347. The examiner can normally be reached on Mon-Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leon B Lankford, Jr
Primary Examiner
Art Unit 1651

Laura Schuberg